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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,246	01/03/2002	Toshiaki Takezawa	2001-1784A	1296

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,246	TAKEZAWA ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-23* is/are pending in the application.

4a) Of the above claim(s) *14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 and 8-13 as amended (12/03/2004) are under examination in the instant office action.

Claims 14-23 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s).

Claim Rejections - 35 USC § 112

New matter

Claims 1-6 and 8-13 as amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "not to exceed" (see claim 1) has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of using some upper limit for tissue thickness as a critical value.

Although the specification discloses generic ranges 1-50 μM or 4 -20 μM for thickness of tissue sections (page 20, last line), there is no teaching in the as-filed specification that upper limit of 50 μM is a critical and meaningful value as encompassed by the phrase "not to exceed" 50 μM. There is no sufficient support for criticality and for specific functions/effects of any particular upper limit(s) in the applicants' invention as disclosed. This is a matter of written

description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of phrase "not to exceed" is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-11 and 13 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,919,624.

Claims are directed to a tissue section-containing carrier wherein the carrier comprises an animal tissue section with thickness up to 50 μm thick and attached to a support. Some claims are further drawn to the use of various support materials including glass, plastic, etc. Some claims are further drawn to the use of tissue that is fixed, processed for acellularization, embedded. Some claims are directed to the use of tissue derived from born mammalian animal.

US 5,919,624 discloses cervical tissue sections having thickness 4 μm or 8 μm or 50 μm depending on the intended tissue testing (col. 12, lines 5-25). The sections are attached to various support materials including glass or plastic containers. The tissue sections are fixed, paraffin-embedded and, thus, they are processed for acellularization. The tissue sections are derived from

adult patients or born mammalian animals. Thus, the cited patent anticipates all claimed elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8-13 as presently amended are rejected under 35 U.S.C. 103(a) as being obvious over Mori et al. {Anat Embryol (1999) 199:319-327} and/or by WO 99/12555 taken with US 5,919,624 and US 3,785,234.

Claims are directed to a tissue section-containing carrier wherein the carrier comprises an animal tissue section that is 50 μm thick and that is attached to a support. Some claims are further drawn to the use of various support materials including glass, plastic, etc. Some claims are further drawn to the use of tissue that is fixed, treated with reagents to modify its structure or that is embedded. Some claims are directed to the use of tissue derived from fetal or postnatal mammalian animals.

The reference by Mori et al discloses a tissue section-containing carrier or a tube wherein the tube comprises an animal tissue section that is a preparation of mouse fetal or postnatal liver tissue section. The liver tissue is cut into 240 μm thick slices. The tissue sections are mounted in a plasma clot on cover glass and, thus, attached to the support treated in order to promote tissue adhesion (page 320, col. 1, par. 2) and/or embedded in resin. The liver tissue sections are live

and growing. The liver tissue sections are further fixed with methanol and treated with antibody (page 320, col. 2, par. 3).

WO 99/12555 discloses a cell culture carrier or a well plate comprising an animal tissue section such as submucosal tissue attached to a plastic support or holder (example 3, pages 17-18) and that is used for animal cell culture. The tissue section of the cited patent has been demonstrated to support grown of other cells (page 18, at results). The plastic holder is flat in order to keep the tissue flat and thus, it is treated to promote tissue adhesion within the meaning of instant claims. The submucosal tissue is treated with enzyme galastosidase to remove surface epitopes and, thus, to modify tissue microstructure within the meaning of the instant claims. The cited patent teaches that the collection of submucosal tissue preparations includes freezing (page 12, line 29) and also includes treatment with antibodies (page 14, line 4) at least for the purpose of quality control of the submucosal tissue samples. The submucosal tissue preparations are obtained from mammalian animals (page 4, line 18). Although the cited document does not explicitly indicate whether born or unborn animals were used for tissue collections, it is reasonably to assume that both born and unborn animals have submucosal tissues and, thus, the submucosal tissue preparations used in the cell culture carrier of cited patent meets the meaning of instant claims 12 and/or 13.

Therefore, the reference by Mori et al discloses that tissue is cut into 240 μm thick slices. WO patent is silent about thickness of tissue sections. However, both preparations capable to maintain animal cell culture growth regardless their thickness.

The additional references demonstrate that equipment to cut thin tissue sections is available (US 3,785,24 at col.1, lines 10-15) and that thickness of tissue sections is modified accordingly to the intended testing (see US 5,919,624 at col. 12, lines 5-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain tissue sections of various thickness with a reasonable expectation of success in culturing animal cells. One of skill in the art would have been motivated to modify thickness of tissue sections with regard to design of culture containers, for example, or with regard to further evaluation of tissue sections as suggested by US 5,919,624 for various testing protocols. One of skill in the art would have been motivated to decrease thickness of tissue sections for the expected benefits in visual evaluation of tissue section under microscope, for example.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 12/03/2004 have been fully considered but they are not persuasive.

With respect to the reference by Mori et al. applicants argue that it discloses that a tissue section is cut into 240 μm slices but not into 50 μm slices as presently claimed and, thus, it is different from the applicants' invention (response page 8). However, although the cited tissues

section has thickness different than the claimed tissue section thickness, the cited tissue section is live and growing and, thus, the differences in tissue thickness do not affect biological properties of tissue section as intended for culture of animal cells within the broadest meaning of the instant claims. The criticality of tissue section being up to 50 μm thick is uncertain as argued and as disclosed. Applicants also argue the claimed tissue section "may perform acellurization processing". The tissue section in the Mori reference has been further treated or fixed and, thus, it is further rendered acellular or dead within the broadest meaning of claims and arguments. Applicants appear to argue that the claimed tissue section is capable to support growth of some other cells. However, the cited tissue section is live and growing and thus, capable to produce cytokines and/or active agents that are reasonably expected to support growth of other cells within the broadest meaning of claims and arguments. The instant claims are not limited to any particular cells or tissues.

With respect to WO 99/12555 applicants' arguments are the same as for the teaching by Mori (response page 9). However, the criticality of tissue section being 50 μm thick is also uncertain as argued, particularly in view that the tissue section of the cited patent has been demonstrated to efficiently support the grow of other cells. Applicants also argue that it is unnecessary to enzymatically treat the tissue section. Yet, some of the claims are drawn to enzymatic treatment (claim 8).

Therefore, applicants' arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicants' arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

February 9, 2005

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER